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10/535,529

05/09/2006

Samir F. Saba

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MEDLEN & CARROLL, LLP

101 HOWARD STREET

SUITE 350

SAN FRANCISCO, CA 94105

EXAMINER

EVANSKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

01/19/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,529

Applicant(s)

SABA, SAMIR F.

Examiner

George R. Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10, 27-29, 31, 33-41, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 31 and 33-41, 43, 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 6-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 11/16/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-29, 31, 33-41, 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27 (and similarly claim 37), line 5, "wherein said device is configured..." is vague since the device comprises three elements, a), b), and c), and it is unclear what element is actually configured to determine an earliest arriving signal. In line 6, "detected by said....electrodes" is vague since the electrodes have not been set forth to detect electrical signals.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 31, 33, 34, 36, 37, 40, 41, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Lu (6654639). Lu discloses the claimed invention as having multiple atrial and ventricular distal tip electrodes (e.g. figure 1) for a pacemaker (e.g. abstract) and defibrillator (e.g. shocking circuit 116), with timing device (e.g. microcontroller 60 comprised of arrhythmia detection, timing control, and morphology detector) used to diagnose the origin of the arrhythmia, such as SVT or VT, from the earliest arriving electrical signal (e.g. columns 11-13). Note that Lu's system and method is capable of meeting the functional use recitations presented in the claims of delivering simultaneous pacing bursts from the electrodes and detecting the earliest signal since Lu's electrodes are capable of delivering pacing pulses and do detect the earliest signals and that the claims have not set forth any element to actually generate and deliver the simultaneous pulses.

Claims 27-29, 31, 33, 34, 36-41 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable Kupper (6813518) in view of Lu (6654639) or Ideker et al (6243603). Kupper discloses a pacemaker/defibrillator to deliver simultaneous pacing burst pulses to the atrium and ventricle when a tachycardia is detected (e.g. abstract, figures 6, 7, col. 11, line 53), using multiple leads/electrodes and thereafter senses for the first atrial or ventricular depolarization (e.g. col. 11, line 64, figure 3, element 74/58) to determine the first depolarization to provide

different intervals (e.g. escape intervals, col. 10). Figure 5 shows a timing device as element 63 that is used to set the pacing escape intervals. These intervals are used to set pacing escape intervals (e.g. V-V, V-A, A-V, and A-A) for the different pacing modes and to determine arrhythmias and the device necessarily does determine the earliest arriving electrical signal since following therapy it waits to sense a ventricular or atrial event (e.g. cols 9-11). In addition, the leads of Kupper necessarily have separate conductors since they are separate leads and deliver signals and sense from separate electrodes.

Kupper does state in column 10, line 40 that any tachy detection algorithm presently known in the art can be used in his device but does not disclose the specific algorithm of using the timing device to identify that said origin of an arrhythmia from the earliest arriving electrical signal is a SVT, VT OR AV nodal tachy. Lu or Ideker disclose a timing device to identify that said origin of an arrhythmia from the earliest arriving electrical signal is a SVT, VT or AV nodal tachy to identify the origin to deliver appropriate therapy based on the diagnosis of origin and to the appropriate heart chamber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the therapy system and method as taught by Kupper, the timing device to identify that said origin of an arrhythmia from the earliest arriving electrical signal is a SVT, VT or AV nodal tachy as taught by Lu or Ideker since such modification would provide the predictable results of delivering appropriate therapy based on the origin and to the appropriate heart chamber.

Claims 28, 29, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu in view of Kupper. Lu discloses the claimed invention except for the microprocessor

configured to initiate simultaneous ATP bursts. Kupper teaches that it is known to use a microprocessor configured to initiate simultaneous ATP bursts to effectively treat AF. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lu, with the microprocessor configured to initiate simultaneous ATP bursts as taught by Kupper since it would provide the predictable results of a pacing system that effectively treats AF.

Claims 35 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu or modified Kupper (Kupper in view of Lu or Ideker). Lu or modified Kupper discloses the claimed invention except for the quadripolar sensing lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD as taught by Lu or modified Kupper, with the quadripolar sensing lead since it was known in the art and the examiner is taking official notice that IMDs use quadripolar sensing leads to provide the predictable results of allowing multiple areas of the heart to be sensed with one lead by inserting a minimal number of leads and therefore providing less trauma/problems to the heart.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. Claims 27 and 37 only contain a timing device to identify the origin of arrhythmia and do not contain an element to deliver the simultaneous pulses or provide a nexus/relationship between the delivery of the simultaneous pulses, detection of the earliest arriving pulse and identification of origin.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571 272 4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
1/17/11